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10/518,383	12/29/2004	Alain Sanson	263864US0X PCT	6816
22850	7590	04/08/2010	EXAMINER	
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P.			GUPTA, ANISH	
1940 DUKE STREET				
ALEXANDRIA, VA 22314			ART UNIT	PAPER NUMBER
			1654	
			NOTIFICATION DATE	DELIVERY MODE
			04/08/2010	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/518,383	<b>Applicant(s)</b> SANSON ET AL.
	<b>Examiner</b> ANISH GUPTA	<b>Art Unit</b> 1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 19 January 2010.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 4-62 is/are pending in the application.

4a) Of the above claim(s) 10-14, 17 and 18 is/are withdrawn from consideration.

5) Claim(s) 4,5,8,9 and 36-39 is/are allowed.

6) Claim(s) 6,7,15,16,19-35 and 40-62 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election of Group I, claims 1-9, 15-16, and 19-61 in the reply filed on 2-11-08 is acknowledged. The requirement is still deemed proper and is therefore made FINAL.

Applicants also elected the species of SEQ ID NO 1, without any labels. A search was done for SEQ ID NO 1, and it was found to be free of the prior art. Search was extended to SEQ ID NO 2-14 and they too were found to be free of the prior art. In accordance Markush practice, the search was extended to the peptide of SEQ ID 15 of claim 1. This too was free of the prior art. Thus claims 4-9, 15-16 and 19-62 have been examined.

Claims 10-14, 17-18 have been withdrawn from consideration as corresponding to non elected Group.

2. The rejection of claims 2, 6-7, 15-16, 19-35, 40-62, rejected under 35 U.S.C. 112, second paragraph, as being indefinite is hereby withdrawn in view of Applicants amendments to the claims.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 6-7, 15-16, 19-35, 40-62 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in

the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims have been amended from J represents amino acids to all the J variables defined by specific amino acids. Thus, now J26 is defined as Leu, Val or Ile, J64 as Phe, Leu or Met, etc. . . . New claim defines all of the J variables with specific amino acids in each J variable position. This amendment to the claims constitutes new matter.

#### **Lack of Literal Support**

The originally filed disclosure discloses J an natural amino aids, “in such a manner that at least 50% of them are polar residues chosen from Arg, Asn, Asp, Cys, Gln, Glu, Gly, His, Lys, Orn, Pro, Ser, Thr, and Tyr (see page 11). Furthermore, the specification state that all J's can be chosen from Ala, Arg, Asn, Asp, Cys, Gln, Glu, Gly, His, Ile, Leu, Lys, Met, Orn, PHe, Pro, Ser, Thr, Trp, Tyr, and Val (see page 15 of the specification). However the specification does not specifically recite that J 26, for example, is only Leu, Val, Ile. There is no literal support for the specific J variables as claimed in claim 1 and new claim 30. Furthermore, the originally file disclosure requires the presence of J36. However, the claims do not contain the variable J36 in the sequence. The specification does not provide any support to delete variable J36.

#### **Lack of Inherent Support**

“While there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure.” MPEP 2163. The originally filed disclosure does not provide either implicit or inherent support for the new limitations. There is no guidance within the specification that J variable have specific amino acid substitutions as now currently claimed. The specification generally teaches that J variables are surface amino acids or

residues of this peptide when it is in the folded and active conformation. However this does not lead on of ordinary skill in the art to envision that J are very specific residues as currently claimed. The specification only describes the J's in a general manner without any specificity with respect specific amino acid at any given J position.

The specific example and species also do not provide any implicit or inherent support for the markush for the J variables as now claimed. The specification discloses fourteen specific amino acid sequences. These fourteen amino acid sequences do not adequately represent the variability of the claimed genus. For example, the claimed invention states that variable J74 can be Arg, Asn, Asp, Cys, Gln, Glu, Gly, His, Lys, Orn, Pro, Ser, Thr, Tyr. However, the none of the examples have amino acids that contain a Cys, Lys, Pro or Orn, for example, in position J74. This is also true of other positions within the markush. Furthermore, the species do not provide support for all of the differing combinations of the J variables. There are no species that have Orn in more than one J position. For that matter, there are no species that contain a single Orn residue in any position. Thus, the claims for provide implicit support for the new markush group. Furthermore, there is no support for the deletion of the variable J36 within the sequence. The newly added markush requires that J36 not be present within the sequence. However, all of the species require the presence of an amino acid corresponding to J36.

#### **Applicants Arguments**

Applicants argue that J amino acids are surface amino acid when it is in a folded and active conformation. Applicant's justification to narrow the scope of the J is that they "have compared the sequence of SEQ ID NO: 1-14 . . . and determined" the J variables based on the presence of specific amino acids in the different J locations. Applicants assert that the based on SEQ ID NO 1-

14 the amino acids have been divided into three different Groups. Applicants state that “[t]he feature concerning group I and group 2 have been previously introduced in the claims” and “[o]ne skilled in the art knows from Group I the precise location of these polar amino acids J and also knows that the last 5 polar amino acids cannot be selected from Group 2 but must be selected among the other amino acids which constitute Group 3.”

Applicants argument have been fully considered but have not been found persuasive.

Applicant addition of claim 62, in the response dated 7/08/09, created a new sub-genus which specifically defined the J variables. As stated above, this newly crafted sub-genus has not been adequately supported by the originally filed specification. Similar issues have been addressed by the Federal Circuit. For example, in In re Ruschig, 379 F.2d 990, 154 USPQ 118 (CCPA 1967), the Court rejected a claim to species that fell within a large genus. The Court analogized the genus of the compounds to a forest and the species to a tree. The Court stated “It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail . . . to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees. We see none.” Ruschig, 154 USPQ at 122. Similarly, in Fujikawa v. Wattanasin, 93 F.3d 1559, 39 USPQ2d 1895, the Federal Circuit declined to finds support for a sub-genus based on the discloser of a genus because the application did not contain “blazemarks” to support the subgenus. In justification for denying support, the Court stated that “just because a moiety is listed as one possible choice for one position does not mean there is *ipsis verbis* support for every species or sub-genus that chooses that moiety.” Fujikawa, 39 USPQ2d at 1905. Thus, it is clear from these decisions that the specification must provide blazemarks to the new sub-genus or species.

Here, Applicants have stated that they reviewed SEQ ID NO 1-14 and arrived at the specific J variables because each J variable as recited occurred in at least one sequence of SEQ ID NO 14. However this does not establish written description for the claimed sub-genus. The new sub-genus contains hundreds of sequences beyond those of SEQ ID NO 1-14. For example, the new sub-genus is inclusive of species where J1 is His, J2 is Gly, J3 is Asn, J4 is Val. None of the 14 amino acid taught in the specification contain a sequence HGNV as the first four amino acids within the sequence. In fact only one sequence contains a Histidine residue as the first amino acid and this sequence does not contain a Gly as the second residue, Asp or Ser in the third residue. Yet all of these sequences are encompassed by the claims. The specification does not provide any “blaze mark” that would lead one to conclude that the genus taught in the originally filed claims would be inclusive of the sub genus now claimed. Moreover, the mere fact that the specification contains specific sequence that contain specific amino acid in certain J positions does not lead to possession of any peptide contain those amino acids. As stated above, just because a moiety is listed as one possible choice for one position does not mean there is *ipsis verbis* support for every species or sub-genus that chooses that moiety.

Applicants provide an explanation of the new sub-genus by distinguishing them in three different Groups. However, the specification, as filed, simply fails to describe any structural analysis and the specific amino acid that fall within Group I, II or III based on SEQ ID NO 1-14 as argued by Applicants. In fact, there is simply no mention of any Groups that the J variables may fall into. Further, it is unclear how one of ordinary skill in the art would conclude that Group I, for example, would contain Arg, Asn, Asp, Cys, Gln, Glu, Gly, His, Lys, Orn, Pro, Ser, Thr, Tyr in positions J1, J3, J13, J21, J27, J31, J33, J34, J36, J45, J49, J51, J61, J63, J66, J74, and J75. The specification does not mention Venn diagrams of implies the use of Venn diagrams that would lead one to conclude

that the amino acid substitutions are grouped into three different Sub Groups. The specification simply fails to provide support for the claimed sub-genus.

The rejection is maintained.

4. Claims 4-5, 8-9, 36-39 remain allowed.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.

/Anish Gupta/  
Primary Examiner, Art Unit 1654